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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,607	04/15/2004	Jay N. Cohn	102258.288US3	6389

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1609	

NOTIFICATION DATE	DELIVERY MODE
09/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/824,607	COHN ET AL.	
	Examiner	Art Unit	
	Darryl C. Sutton	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/05/2004, 9/02/2004, 9/22/2004, 11/15/2004.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. (N. Eng. J. Med., 1991).

The claims are drawn to a kit for the treatment of Black patients with a hydralazine compound or salt thereof, and isosorbide dinitrate.

Cohn et al. teaches a method for treating congestive heart failure in Black and White patients with hydralazine and isosorbide dinitrate. (see page 305, Table1); and that some of those treated suffered from hypertension (page 305, Table 1). Cohn et al. teaches that an improvement in mortality was seen in patients treated with hydralazine and isosorbide dinitrate (see page 307, 2nd column, first paragraph) and that oxygen consumption was increased (see page 306, "Exercise Tolerance"). Cohn et al. teaches that hydralazine was administered in tablet form at a dosage of 300 mg/day, and that isosorbide dinitrate was administered in tablet form at a dosage of 120 mg/day (page 304, 2nd paragraph). Cohn et al. also teaches that the different effects of a treatment regimen with the ACE inhibitor, enalapril, (enhanced mortality) and that of a treatment with hydralazine and isosorbide dinitrate (significant improvement in exercise

performance and left ventricular function) suggests that the profile of effects might be enhanced by using the regimens in combination (page 303, Abstract); and that the mechanism of treatment for the two regimens is partly independent (page 307, 2nd column, 2nd paragraph). Cohn et al. teaches the use of hydralazine and isosorbide dinitrate in conjunction with digoxin and diuretics (page 303, 2nd column, 1st paragraph).

Cohn et al. does not teach the pharmaceuticals in a kit to use in their methods. Cohn et al. does not teach the use of hydralazine hydrochloride in their methods. Cohn et al. does not teach the two pharmaceuticals together in a composition, or the pharmaceuticals in sustained release dosage form.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Cohn et al. to use hydralazine hydrochloride for the hydralazine source, since hydralazine hydrochloride is known in the art to be combined with other compounds for the treatment of congestive heart failure, hypertension, and pulmonary hypertension (Bagley et al., 1998). It also would have been obvious to combine the compositions of Cohn et al. to include enalapril since the two treatment regimens (enalapril alone, hydralazine and isosorbide dinitrate) give distinct positive results when treating patients with hypertension and congestive heart failure and their mechanisms for treatment do not overlap. The modification of the method of Cohn et al. to combine the pharmaceuticals into a composition would have been obvious since they worked in conjunction to treat the patients and it would be easier to administer instead of administering 2 separate pills on different time schedules. Modifying Cohn et al. to

include a sustained release dosage would also have been obvious to allow for the pharmaceuticals to be administered on a reduced schedule, and to allow for a relatively constant concentration of the pharmaceuticals in the blood. It would also have been obvious to combine the pharmaceuticals into a kit to perform the methods of Cohn et al. since packaging of pharmaceuticals with medical benefit is routine procedure in the pharmaceutical industry. The inclusion of instructions does not add to the structure or function of the kit, and therefore does not further limit the claims of a kit.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6784177 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the kits of the instant application contain the pharmaceuticals as claimed in the methods of said patent.

Claim 1 of said patent and claims 1 and 12 of the instant application are obvious over one another because the same pharmaceuticals at the same dosages of those of the said patent are contained in the kit of the instant application and are to be used for the identical purpose, the treatment of Black patients. If mortality associated with heart failure is reduced by the pharmaceuticals, the Black patient is treated. At the time

of the invention, it would be obvious to one of ordinary skill in the art to combine the pharmaceuticals required to perform the method of treatment of claim 1 of said patent into the kits of claim 1 and 12 of the instant application since it is common practice in the pharmaceutical industry to combine pharmaceuticals that are to be administered in combination into a kit.

Claims 27-29, 31, 36-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 5-6, and 46 of U.S. Patent No. 6465463 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the kits of the instant application contain the pharmaceuticals as claimed in the methods of said patent.

Claim 3, 5, 6 and 46 in said patent and claims 27-29, 31, 36-37 and 39 of the instant application, are seen as obvious over one another because the same pharmaceuticals of said patent, hydralazine compounds of formula I and isosorbide nitrate or isosorbide mononitrate, are contained in the kit of the instant application and are to be used for the identical purpose, treatment of a Black patient. At the time of the invention, it would be obvious to one of ordinary skill in the art to combine the pharmaceuticals required to perform the method of treatment of claims 3, 5-6, and 46 of said patent into the kits of claim 27-29, 31, 36-37 and 39 of the instant application since it is common practice in the pharmaceutical industry to combine pharmaceuticals that are to be administered in combination into a kit.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on M-Th from 8:00AM-4:00PM EST at (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DCS

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER